No. 94-372

IN THE
Supreme Court of the United States
OCTOBER TERM, 1994

DONNA E. SHALALA, SECRETARY OF HEALTH AND HUMAN SERVICES,
Petitioner,

v.

MARGARET WHITECOTTON, *et al.*,
Respondents.

On Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

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AMERICAN ACADEMY OF PEDIATRICS AS *AMICUS CURIAE* IN SUPPORT OF PETITIONER

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AMERICAN ACADEMY OF PEDIATRICS AS *AMICUS CURIAE* IN SUPPORT OF PETITIONER

INTEREST OF *AMICUS CURIAE*

The American Academy of Pediatrics (the "Academy") is a national non-profit medical specialty society of more than 45,000 board-certified pediatricians. Its principal purpose is to promote the attainment by all children of their full potential for physical, mental and social health. To that end, the Academy advocates for children and their right to medical care through various means, including the adoption of professional policies, educational programs, efforts to influence social and governmental policy and, occasionally, litigation.

The Academy participated prominently in the development of the National Childhood Vaccine Injury Act of 1986 (the "Act"), the interpretation and application of

which are at issue in this case. By significantly enlarging the number of persons entitled to compensation under the Act through including those injured by means other than vaccination, the decision below threatens childhood immunization in the United States, and as a consequence, children's health.

SUMMARY OF ARGUMENT

Congress established a Vaccine Injury Compensation Program (the "Program") to create a compensation system that was not so burdensome to manufacturers as to be a disincentive for vaccine production and to compensate those few children injured by vaccines. The decision below misconstrues the eligibility requirements for compensation under the Program and, by extending the possibility of compensation to children injured by causes other than vaccines, undermines the purposes and threatens the fiscal integrity of the Program.

While expressing no opinion as to respondents' rights, the Academy urges the Court to reject both interpretations of the National Childhood Vaccine Injury Act announced by the court of appeals. The court erred in holding, first, that a presumption of eligibility for compensation can be established when manifestations of injury *preceded* vaccination and, second, that the government can overcome such a presumption only by proving the *cause*—not merely the existence of—the factor other than vaccination that caused the injury.

The first holding is inherently illogical. Given the state of medical knowledge, the second could not be satisfied in many instances where vaccines, in fact, played no role in a child's injury. Most significantly, neither the plain meaning of the Act nor its legislative history supports these interpretations.

ARGUMENT

I. THE NATIONAL CHILDHOOD VACCINE INJURY ACT COVERS ONLY INJURIES PRESUMED OR SHOWN TO HAVE BEEN CAUSED BY THE ADMINISTRATION OF VACCINE. THUS, THE COURT OF APPEALS ERRED IN HOLDING THAT A PRESUMPTION OF ELIGIBILITY FOR COMPENSATION CAN BE ESTABLISHED UNDER THE ACT WHEN INJURY PRECEDED VACCINATION.

In response to a public health crisis, Congress enacted the National Childhood Vaccine Injury Act of 1986 (Public Law 99-660), which was intended to address two pressing concerns; namely,

> (a) the inadequacy—from both the perspective of vaccine-injured persons as well as vaccine manufacturers—of the current approach to compensating those who have been damaged by a vaccine; and (b) the instability and unpredictability of the childhood vaccine market.[1]

The Act establishes the National Vaccine Injury Compensation Program, a method of compensating persons presumably injured by vaccines. Under the Act, a petitioner for compensation may establish causation in either of two ways. The first is to demonstrate that an injury or death meets criteria set out in the statute's "Vaccine Injury Table" (the "Table").[2] The Table, which is based on medical evidence, defines certain vaccine-related injuries and prescribes time limits following vaccination

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[1] H.R. Rep. No. 908, 99th Cong., 2d Sess. pt. 1, at 7 (1986) ("House Report"). On the floor, both Senator Kennedy (Congressional Record, October 18, 1986, at S17345) and Representative Waxman (Congressional Record, October 17, 1986, at H11589) noted that as a result of civil litigation over vaccine injuries a few plaintiffs received large awards while most received nothing, and that vaccine manufacturers' price increases to cover liability costs were threatening to leave the United States without sufficient access to vaccines.

[2] 42 U.S.C. § 300aa-14.

within which they must occur if compensation is to be awarded. Once a petitioner has proven that his or her injury fits within the Table, the burden shifts to the government to prove that a factor other than the vaccine caused the injury. A petitioner whose injury does not meet the Table criteria is entitled to no presumption and must use other means to establish causation.

The court below, relying primarily on a heading in the Table and ignoring the language of the Act itself, has greatly expanded the scope of the Act. The court's interpretation is supported neither by the Act's plain meaning nor legislative history, requires more certainty than is medically possible, and threatens the fiscal integrity of the compensation Program.

In reporting the Act (H.R. 5546) favorably to the House of Representatives, the Committee on Energy and Commerce stated that "The bill establishes a compensation system for those persons injured by routine pediatric vaccines" and that the Act was "intended to compensate persons with recognized vaccine injuries. . . ." [3] Referring to the type of injury at issue in this litigation, the Report stated that:

> if the cause of an encephalopathy is an infection or another condition not related to the vaccine, the encephalopathy is not to be considered compensable.[4]

Thus, it is clear that Congress intended to compensate *only injuries presumed to have been caused by the administration of vaccines.*

The Committee reported also that "a finding of causation is deemed to exist for those injuries listed in the Table which occur within the time period set forth in the Table." [5] For other injuries, a petitioner "must affirmatively demonstrate that the injury or aggravation was caused by the vaccine." [6]

[3] House Report at 12.

[4] House Report at 19.

[5] House Report at 15.

Contrary to Congress's intent, however, the court of appeals held that a child who displays symptoms of a Table injury within the specified time after vaccination establishes a presumption of causation even if the injury—and previous manifestations of it—occurred *before* vaccination. In so holding, the court relied on the fact that:

> Nowhere does the statute expressly state that proof of a Table encephalopathy includes a showing that the child sustained no injury prior to administration of the vaccine.[7]

Also, the court noted that "the Table language is that the first symptom *after vaccine administration* must occur within Table time, not, as the Secretary argues, the first of all manifestations must so occur." [8]

The court's interpretation, however, is at odds with the House Report in several respects. First, an injury that predates vaccination cannot be one of "those *injuries* listed in the Table *which occur* within the time period set forth in the Table." [9] (emphasis added) Such an injury has, by definition, already occurred. What is observable after vaccination is simply a *manifestation* of the injury. Second, the House Report's statement, quoted above, that causation is to be deemed to exist for Table injuries, in no way indicates that Congress was indifferent to causation or considered it irrelevant to compensation.[10] To the con-

[6] House Report at 15.

[7] *Whitecotton v. Secretary of Dep't of Health and Human Servs.*, 17 F.3d 374, 376 (Fed. Cir.), *cert. granted*, 115 S. Ct. 416 (1994).

[8] *Id.*

[9] See text at note 5.

[10] It is true that a few injuries that occurred before vaccination will doubtless be compensated under the Act. These are injuries that were not recognized before vaccination, but caused Table symptoms within the statutory period, and could not be shown by

trary, the evidence cited above of Congress' intention to compensate only for vaccine injuries, as well as other language from the House Report,[11] demonstrates Congress' wish that the presumption of eligibility not apply in cases of preexisting injuries. Finally, the House Report directly contradicts the court of appeals' interpretation by stating:

> The Vaccine Injury Table sets forth a list of vaccines, injuries, and time periods of *initial onset* of injuries. If a listed injury is *first made manifest* within the time period specified in the Table following the administration of the vaccine listed in the Table, the injury is to be considered compensable. . . .[12] (emphasis added)

Legislative history aside, the text of the statute requires a different result than that reached by the court below. The court of appeals identified two sections of the Act as specifying the time within which Table injuries must occur in relationship to vaccination, and based its holding on its construction of these provisions. In the first reference, an event is described as compensable if:

> the first symptom or manifestation of the onset or of the significant aggravation of any such illness, dis-

a preponderance of evidence to result from another identifiable factor, illness, or condition. Congress understood and accepted the fact that some overcompensation would occur. See note 11 *infra*. However, such overcompensation is simply the unavoidable cost of operating the program in an environment where medical knowledge is less than perfect. Nowhere in the Act or its legislative history did Congress indicate a desire to compensate under the Program individuals who were not actually injured by vaccines.

[11] In defending the presumption as to Table injuries, the Committee recognized the existence of "public debate over the incidence of illnesses that coincidentally occur within a short time of vaccination" and suggested that revisions to the Table should be entertained when more information on vaccine effects became available. The House Report stated that the Act "does not include compensation for conditions which might legitimately be described as preexisting". House Report at 15.

[12] House Report at 19.

> ability, injury, or condition or the death occurred within the time period after vaccine administration set forth in the Vaccine Injury Table. . . .[13]

The plain meaning of this provision, as the court of appeals recognized,[14] is that the symptom or manifestation must have occurred *for the first time* following vaccination. Under this language, an injury that was manifest before vaccination would not qualify for compensation.

The other reference or references[15] cited by the court of appeals are located in the Table section of the Act, 42 U.S.C. § 300aa-14(a). One of the two references in that section appears in the paragraph introducing the Table and the other, which is nearly identical and on which the court relied,[16] is simply the heading above a column of time periods. The heading reads:

> Time period for first symptom or manifestation of onset or of significant aggravation after vaccine administration:[17]

The court of appeals construed this heading as meaning that events preceding vaccination are irrelevant. That is, a listed symptom occurring within the specified time *after* vaccination satisfies the Table, no matter how often the same symptom occurred before vaccination. Having concluded that the provisions of the two sections conflict, the court elected to honor the Table section, for no stated reason other than that Congress could have "expressly

[13] 42 U.S.C. § 300aa-11(c)(1)(C)(i).

[14] *Supra* note 7, at 376.

[15] The court of appeals cited the Table section for its interpretation, without stating that the section contains two iterations of the time requirement. *Whitecotton v. Secretary of Dep't of Health and Human Servs.*, 17 F.3d 374 at 376.

[16] *Id.*

[17] 42 U.S.C. § 300aa-14(a).

made the absence of preexisting injury an element of the prima facie case had it so intended." [18]

In fact, however, the provisions on time of occurrence in the two sections of the statute construed by the court of appeals [19] do not conflict, if one recognizes that what has already been stated completely in the text of a statute need not be fully repeated in a table.[20] The Table heading that the court of appeals quotes is a summary or shorthand for the complete statement found in the text of the Act at 42 U.S.C. § 300aa-11(c)(1)(C)(i), which precedes the Table section. The Table heading should be read as a reference to the earlier provision, rather than as a restatement in full or, as the court of appeals maintained, an alteration of the text's meaning *significantly* by omission of a portion of the text requirement. Further support for this interpretation lies in the general rule of statutory construction that provisions within the body of a statute are to be read together and an effort must be made to harmonize provisions with one another and with the purpose of a statute.[21]

In addition to the references discussed above, a third section of the Act refers to the time in which injury occurs. This section of the Act, which the court of appeals ignored in its decision, reads in relevant part:

> The . . . court may find the *first symptom* or manifestation of onset . . . occurred within the time period described in the Vaccine Injury Table even though

[18] *Supra* note 7, at 376.

[19] 42 U.S.C. § 300aa-11(c)(1)(C)(i) and 42 U.S.C. § 300aa-14(a).

[20] Usually, a table summarizes information available elsewhere. The word is defined as "a systematic arrangement of data usually in rows and columns for ready reference" and "a condensed enumeration". *Webster's Ninth New Collegiate Dictionary.*

[21] Norman J. Singer, *Sutherland Stat. Const.* (5th ed.) § 47.06. *Purview provisions*, citing *Murphy v. Nilsen*, 19 Or. App. 292, 527 P.2d 736 (1974). See also § 46.05. *"Whole statute" interpretation*, quoting *Sturges v. Crowninshield*, 17 U.S. 122, 202 (1819).

> the occurrence of such symptom or manifestation was not recorded or was incorrectly recorded as having occurred outside such period.[22] (emphasis added)

This third section's reference, which also precedes the Table section, bolsters the Academy's and the government's argument. Why should it be expected that the Act, having stated twice already in text that the first symptom or manifestation of a compensable injury must occur after vaccination, would repeat that statement at full length in the Table heading?

II. THE COURT OF APPEALS ERRED IN HOLDING THAT THE GOVERNMENT MUST PROVE, NOT MERELY THAT A FACTOR OTHER THAN VACCINATION CAUSED THE INJURY, BUT ALSO THE PRECISE CAUSE OF THE CAUSATIVE FACTOR.

The court of appeals' second holding addresses the government's ability to overcome the presumption of eligibility established by a petitioner who meets the Table requirements. The court would allow the government to defeat the presumption only if the Secretary can prove the specific cause—not merely the existence of—a preexisting condition that is shown by a preponderance of the evidence to have caused the injury. Again, the plain meaning of the statute does not support this holding. Moreover, a later decision of the same court appears to reject it.

Once a petitioner has met his or her initial burden, Congress specified that the government have an opportunity to demonstrate that injury resulted from other factors. The Act provides that compensation is due if petitioner meets his burden and the government fails to prove by

> a preponderance of the evidence that the illness, disability, injury, condition, or death described in the

[22] 42 U.S.C. § 300aa-13(b)(2).

> petition is due to factors unrelated to the administration of the vaccine. . . .[23]

Next, the Act limits what evidence the government may use, as follows:

> the term "factors unrelated to the administration of the vaccine"—(A) does not include any idiopathic, unexplained, unknown, hypothetical, or undocumentable cause, factor, injury, illness, or condition. . . .[24]

In short, the government must prove that the petitioner's injury emanated from a source other than the vaccine, not simply speculate as to that possibility. The government thus may not disclaim knowledge of what caused a child's symptoms after vaccination and thereby deny compensation.

The Act provides, however, that if the government *can* prove that another factor caused the injury, the petitioner's request for compensation must be denied. The Act contains no requirement that the Secretary also prove what caused the other factor. As is explained below, and as Congress surely knew, the cause or causes of many conditions affecting children before and soon after birth are not fully comprehended, though the conditions are known to occur and are readily recognized.

In September, 1994, another panel[25] of the Court of Appeals for the Federal Circuit reached a different decision on this point than that in the case under review. In *Knudsen v. Secretary of Dep't of Health and Human Servs.*, (*Knudsen*)[26], the court held that the government

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[23] 42 U.S.C. § 300aa-13(a)(1)(B).

[24] 42 U.S.C. § 300aa-13(a)(2)(A).

[25] *Whitecotton v. Secretary of Dep't of Health and Human Servs.* was decided by Judges Newman and Mayer; *Knudsen*, by Chief Judge Archer and Judge Nies. Judge Clevenger was a member of both panels.

[26] 35 F.3d 543 (Fed. Cir. 1994).

could defeat a compensation claim by offering proof of an alternative cause of injury—there, a viral infection—although the cause of the infection was unknown. In the court's words:

> there is nothing in the Vaccine Act that requires a *per se* rule that alternative causation cannot be proved when the specific virus is not identified. Accordingly, we hold that a "viral infection" *can* be an alternative causation, even though the viral infection is not in the particular case specifically identified by type or name.[27]

Knudsen's holding on this point is correct, because it allows the government to prevail if it proves that the vaccination at issue did not cause the claimant's injury. Requiring more, as the court below has done in this case, goes far beyond what is necessary to disprove the vaccine's connection to the injury.

III. THE COURT OF APPEALS' SECOND HOLDING IS MEDICALLY UNWORKABLE.

The court of appeals' second holding, that only preexisting conditions with known causes can overcome a petitioner's presumption of eligibility, would have serious implications for the nation's vaccine program. Unfortunately, so little is known of the causes of prenatal and perinatal injuries that under the court of appeals' holding a presumption once established would be inordinately difficult to defeat.

Medical literature is replete with acknowledgments of ignorance and uncertainties by eminent researchers as to the causation of birth defects and perinatal injury and illness. The examples immediately following are selected from a compilation of major studies published by the National Institutes of Health. Together, these statements demonstrate that the government frequently could not

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[27] *Id.* at 549.

satisfy the court of appeals' order to show the cause of the "factor unrelated" to the vaccine that is responsible for a child's injuries.

> The infectious diseases of major importance to the developing nervous system are rubella, cytomegalovirus, herpes simplex and toxoplasmosis. In addition, there is circumstantial evidence that in a significant number of instances the developing nervous system is damaged by unidentified infectious agents.[28]
>
> Approximately 3 percent of children have major malformations . . . present at birth. . . . The cause of most malformations is unknown, and only a limited number of drugs, chemicals or toxins have been positively implicated.[29]
>
> [F]or 30-40 percent of developmental defects, knowledge about cause is altogether lacking.[30]
>
> The first question parents of a child with neurologic damage ask their physician is 'What caused the damage?' . . . Even when we know that one event, such as asphyxia, *can* cause neurologic damage, we cannot be certain in most cases that the asphyxia *did* cause such damage.
>
> Physicians usually establish cause of disease by eliminating candidates from the classic disease categories —genetic, metabolic, traumatic, tumor, degenerative, vascular or infectious. But, in infants and children with CP [cerebral palsy] and MR [mental retardation], this method often fails to provide definite evidence of cause.[31]

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[28] Hugo W. Moser, "Biologic Factors of Development", *Prenatal and Perinatal Factors Associated with Brain Disorders* at 146 (John M. Freeman, ed., U.S. Dep't of Health and Human Services, NIH Publication No. 85-1149, April 1985) (*"Prenatal and Perinatal Factors"*).

[29] *Id.* at 142.

[30] *Id.* at 121.

[31] John M. Freeman, "Introduction", *Prenatal and Perinatal Factors* at 2.

> In spite of the many known causes of mental retardation, the exact defect in the majority of individual patients is unknown. . . .[32] The large group of retarded resulting from prenatal causes may be separated into three major divisions: cases due to genetic factors, those due to external factors that impair fetal development, and a large remaining portion of cases of clearly prenatal but otherwise unknown etiology.[33]

An article on congenital defects acknowledges that

> During pregnancy maternal, fetal, and environmental factors may cause microcephaly. Many cases of microcephaly are sporadic and no underlying cause is identifiable. Pathologic conditions that retard brain growth after birth and during the first year or two of life also may lead to microcephaly.[34]

Medicine's present inability to resolve the causation of most early childhood injury of various kinds is even more pronounced than the foregoing suggests. Often, when a cause *can* be identified for a particular child's condition, it is simply a name for a sequence of events that remains mysterious. It is not known, for example, why chromosomal transmutations occur in embryos or by what mechanism they frequently produce mental retardation. A case in point is Down syndrome, a single type of chromosomal abnormality, which accounts for one in three cases of severe mental retardation[35]. With a Down syndrome child, it is possible to know with reasonable certainty that the syndrome (three #21 chromosomes instead of two)

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[32] Harrie R. Chamberlin, "Mental Retardation", *Pediatric Neurology* at 154 (Thomas D. Farmer, ed., Harper & Row, Phila. 1983) (3d ed.)

[33] *Id.* at 155.

[34] Ronald I. Jacobson, "Congenital Structural Defects", *Pediatric Neurology: Principles and Practice* (Kenneth F. Swaiman, ed., The C.V. Mosby Co., St. Louis 1989).

[35] Moser, *supra* note 28, *Prenatal and Perinatal Factors* at 122.

caused a particular injury—for example, respiratory distress. However, it is not known at present what caused the trisomy to occur.

Finally, even in the rare instance where an event frequently associated with neurologic damage is known to have taken place,[36] it cannot be predicted with any degree of certainty that the child in question was injured and will, at some point, exhibit brain damage.[37] The event may have befallen a child stronger or weaker than most [38] and, too, subsequent events may worsen or ameliorate the effects of the original occurrence.[39]

These layers of scientific uncertainty as to causation and effect of perinatal injury render the court of appeals' newly imposed requirement unworkable. Even if the presence of an injury or condition were abundantly clear before vaccination, the government could not, in many instances, establish the cause of the condition. In these cases, the petitioner could recover under the Act even where all parties agreed that the injury was not caused by a vaccine.

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[36] As to birth injuries, "[d]ocumenting damage within the brain at the time it occurs remains a problem. There is limited ability to record what is actually taking place in the brain. . . . Instead, fetal distress is studied indirectly wtih systemic, biophysical, and biochemical techniques." Mortimer G. Rosen, "Factors During Labor and Delivery That Influence Brain Disorders", *Prenatal and Perinatal Factors* at 244.

[37] Task Force on Joint Assessment of Prenatal and Perinatal Factors Associated with Brain Disorders, "National Institutes of Health Report on Causes of Mental Retardation and Cerebral Palsy", 76 *Pediatrics* 457-58, No. 3 (Sept. 1985) (*"NIH Report"*). For a study of this phenomenon with respect to one type of injury and one possible effect thereof, see John M. Freeman & Karin B. Nelson, "Intrapartum Asphyxia and Cerebral Palsy", 82 *Pediatrics* 240-49, No. 2 (Aug. 1988).

[38] *NIH Report* at 458.

[39] Gordon Avery, "Effects of Social, Cultural and Economic Factors on Brain Development", *Prenatal and Perinatal Factors* at 613.

IV. AFFIRMANCE OF THE COURT OF APPEALS' DECISION MAY DISCOURAGE APPROPRIATE VACCINATION OF CHILDREN.

If the court of appeals' erroneous decision is upheld, there may be unintended consequences that could threaten the well being of children. Two bodies presently serve as the primary authorities for advising physicians in the United States on the administration of vaccines to children: the Advisory Committee on Immunization Practices of the United States Public Health Service and the Committee on Infectious Diseases of the American Academy of Pediatrics. In recent years both bodies have issued stronger, more explicit recommendations on the need to immunize children with recognized or suspected neurologic handicaps of known and unknown causation.[40] These stronger recommendations are based on recent scientific information regarding the safety of vaccines,[41] on the entitlement of such children to receive immunization, and on their enhanced risk of exposure to, and complications from, vaccine-preventable diseases.

If the court of appeals' decision remains in effect, these committees may conclude that they are obligated to inform physicians that immunizing children with preexisting conditions can result in liability for the vaccine compensation program, vaccine manufacturers, or the adminis-

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[40] Centers for Disease Control and Prevention, "Diptheria, tetanus and pertussis: recommendations for vaccine use and other preventive measures": *Recommendations of the Immunization Practicues Advisory Committee (ACIP)*, MMWR 1991:40 (No. RR-10) 1-28; *Report of the Committee on Infectious Diseases* 365-67 (American Academy of Pediatrics, Peter G. Peter, ed., Elk Grove Village, Ill.) (23d ed. 1994).

[41] Kathleen R. Stratton, et al., *Adverse Events Associated with Childhood Vaccines* (Institute of Medicine, National Academy Press, Wash. D.C. 1994); Christopher P. Howson, et al., *Adverse Effects of Pertussis and Rubella Vaccines* (Institute of Medicine, National Academy Press, Wash., D.C. 1991).

tering physician.[42] The Academy would, of course, urge physicians to act only on the basis of medical indications for immunization, and presumably most physicians would do so. Still, it would be unreasonable not to expect some influence on physicians' willingness to immunize children with underlying neurologic disorders. Any decrease in immunization would be highly regrettable, because, as noted, children with neurologic impairments are more than usually susceptible to complications of diseases for which vaccination is available.

V. EXPANSION OF THE GROUP ELIGIBLE FOR COMPENSATION UNDER THE ACT THREATENS THE FISCAL INTEGRITY OF THE PROGRAM.

The compensation program established by the National Childhood Vaccine Injury Act of 1986 derives its funding primarily from two sources: for so-called "preenactment" cases (claims associated with the administration of a vaccine prior to the effective date of the compensation law)[43] awards are paid from sums appropriated annually to the Department of Health and Human Services, with a current limitation of $110,000,000 per fiscal year.[44] Claims associated with the administration of a vaccine on or after the law's effective date (so-called "post-enactment" cases), are paid from the Vaccine Injury Compensation Trust Fund.[45] A tax, or surcharge, is imposed on each dose of the various childhood vaccines to keep the Fund

[42] Anyone claiming damages greater than $1000 associated with a vaccine administered after October 1, 1988 must first petition the Federal Court of Claims for compensation, 42 U.S.C. § 300aa-11 (a) (2) (A). After the court has ruled, however, civil actions may be initiated, 42 U.S.C. § 300aa-21 (a).

[43] The effective date is October 1, 1988.

[44] 42 U.S.C. § 300aa-15 (j).

[45] 26 U.S.C. § 9510. The Fund was established by P.L. 100-203, enacted a year after the enactment of the law establishing the National Vaccine Injury Compensation Program.

solvent.[46] Amounts equivalent to the net revenues received in the Treasury as a result of the vaccine surcharge are automatically paid into the Fund.[47]

The per-dose taxes [48] were established by Congress after hearings during which expert testimony was received, estimating necessary individual surcharges based in part on numbers of cases eligible for compensation. *See*, generally *Funding of the Childhood Vaccine Program: Hearing Before the Subcommittee on Select Revenue Measures of the House Committee on Ways and Means*, 100th Cong., 1st Sess. (1987) (Statement of John C. Butler III, Principal, Putnam Hayes & Bartlett, Inc.). Per-dose cost estimates received during the hearing were based primarily upon data on the reported incidence of various types of adverse reactions to vaccines paid for by the public sector; these data were collected by the Centers for Disease Control and Prevention. *Id.*

The Academy shares the government's belief that major expansion of eligibility for compensation would threaten, and could destroy, the compensation program.[49] Because of fiscal caps on funding mechanisms that support both "pre-enactment" and "post-enactment" awards, permitting compensation of other injuries would destroy the economic premise for both the appropriations limitation and the tax and, thus, the program's funding.

[46] 26 U.S.C. § 4131.

[47] 26 U.S.C. § 9510.

[48] The amount of tax imposed is as follows: DPT vaccine—$4.56; DT Vaccine—$0.06; MMR vaccine—$4.44; Polio Vaccine—$0.29.

[49] No. 94-372, *Secretary of Dep't of Health and Human Servs. v. Whitecotton*, Petition for a Writ of Certiorari to the United States Court of Appeals for the Federal Circuit 19-21, asserting that the decision below "could readily require more than $200 million in additional compensation over the next ten years." *Id.* at 20.

In addition, under the Act [50] so-called post-enactment cases must initially be filed with the Federal Court of Claims; no such limitation applies to pre-enactment cases and the claimant may choose between civil litigation and the federal no-fault approach. For fiscal reasons, Congress established a limit of 3500 pre-enactment cases.[51] Thereafter, the no-fault alternative is no longer available to persons injured before passage of the Act. Thus, to expand the compensation system beyond persons presumed to have been injured as a result of administration of a covered vaccine could have the effect of returning many pre-enactment cases to the tort system defeating the principal purpose of the vaccine compensation law.

CONCLUSION

The decision of the Court of Appeals for the Federal Circuit should be reversed insofar as it allows recovery for injuries unrelated to vaccination and prevents proof of causation by another factor unless the cause of the factor is known. *Amicus curiae* takes no position on respondents' entitlement to compensation.

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[50] 42 U.S.C. § 300aa-11(a)(2)(A).

[51] 42 U.S.C. § 300aa-11(b)(1)(B).